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Miami Beach, FL 33139
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APR 2 5 2012

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Sintea Plustek's Posterior Lumbar System
510(k) Summary
March 2012

I. Company: **Sintea Plustek, LLC.**
407 Lincoln Rd. Suite 10L
Miami Beach, FL 33139
(305) 673-6226

II.	**Proprietary Trade Name:**	Sintea Plustek's Posterior Lumbar System
	Regulation Number:	888.3050, 888.3070
	Regulation Name:	Spinal Interlaminal Fixation Orthosis, Spondylolosthesis Spinal Fixation Device System, and Pedicle Screw Spinal System
	Product Class:	Class II
	Product Code:	KWP, MNH, MNI

III. Product Description

As a special 510(k) submission, the predicate device to which we are claiming equivalence is our own product, Sintea Biotech's Posterior Lumbar System Multi-axial Screws - DESCO (K081631). This 510(k) submission represents a modification to the predicate, in which the cross-links and connectors are added to the already cleared system.

IV. Indications

The Posterior Lumber System Multi-Axial Screw DESCO is a posterior, nonpedicle screw system of the noncervical spine indicated for degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, fracture, tumor, pseudoarthrosis, and failed previous fusion.

The Posterior Lumbar System is a pedicle screw system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

The Posterior Lumbar System is a pedicle screw system indicated for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to Sacrum) with removal of the implants after the attainment of a solid fusion.

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V. Device Description

The crosslinks and rod-to-rod connectors are used to connect two rods in a pedicle screw construct. The purpose is to add further stability to the system. The components are made of medical grade, FDA recognized, titanium alloy (ASTM F316). The rigid crosslinks come in sizes ranging from 15mm to 48mm, in increments of 3mm, and the modular crosslinks come in 3 sizes (small 30-38mm, medium 37-52mm, and large 50-70mm), but can lock at any size in between the ranges. The variable flat crosslinks contain 2 components an SX (left) and DX (right). The two are connected by a nut that can lock the connector along any length: small 26.6-33.6mm, medium 36.6-53.6mm, and large 46.6-73.6mm. The cross-links are used to connect parallel constructs along the spinal column to stabilize the system. The rod-to-rod connectors come in domino form and longitudinal. The rod-to-rod connectors will connect two rods in series either along the same axis by utilizing the longitudinal connector or offset the rod laterally by approximately 5.5mm (the diameter of a rod) utilizing the domino connector. The crosslinks and rod-to-rod connectors utilize a nut which threads through the component and comes to contact with the rod to lock the component to the rod along the construct.

VI. Performance Data

The mechanical tests performed on the worst case crosslink construct were performed in accordance with ASTM F1717. The tests performed were static compression, static torsion, and dynamic compression/fatigue. The tests performed on the rod-to-rod connectors were in accordance with ASTM F1798 and included static compression and torsion tests. In all cases, the worst case construct of the new cross-link versions performed better than the previously cleared cross-link. In addition the new version obtained results demonstrating greater stiffness, and higher yield and ultimate strength.

VII. Substantial Equivalence

Sintea Plustek, LLC. has confirmed through FEA and mechanical testing that the additions to the Posterior Lumbar System Multi-axial Screws - DESCO are substantially equivalent to Sintea Biotech's Posterior Lumbar System – DESCO (K081631) with respect to functional design, indications for use, and principles of operation, performance, and materials.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Sintea Plustek, LLC
% Ms. Danielle Wernikowski
407 Lincoln Road, Suite 10L
Miami Beach, Florida 33139

APR 25 2012

Re: K112611
Trade/Device Name: Posterior Lumbar System Multi-Axial Screws - DESCO
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNI, MNH, KWP
Dated: March 19, 2012
Received: March 29, 2012

Dear Ms. Wernikowski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): K112611

Device Name: Posterior Lumbar System Multi-Axial Screws - DESCO

Indications for Use:

The Posterior Lumber System Multi-Axial Screw DESCO is a posterior, nonpedicle screw system of the noncervical spine indicated for degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, fracture, tumor, pseudoarthrosis, and failed previous fusion.

The Posterior Lumbar System is a pedicle screw system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

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Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112611